J. 510(k) Summary

APR 12 2006

Applicant's Name, Address, Telephone, FAX, Contact Information

Advanced Sterilization Products
A Johnson & Johnson Company
Division of Ethicon, Inc.
33 Technology Dr.
Irvine, CA 92618

Contact Person:
Joseph M. Ascenzi, Ph.D., RAC
Sr. Manager, Regulatory Affairs
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Submission Date

March 7, 2006

Trade Name

CIDEX® Activated Dialdehyde Solution

Common Name

Liquid Chemical Sterilant

Classification

Class II

Legally Marketed Equivalent Device

CIDEX® Activated Dialdehyde Solution, K924434

Description of Device

CIDEX Solution is a liquid chemical sterilant/high level disinfectant used for sterilization/high-level disinfection of heat sensitive semi-critical medical devices that cannot be processed by another process. The active ingredient

Indications for Use

CIDEX® Activated Dialdehyde Solution is a liquid chemical sterilant and a high level disinfectant for reprocessing heat sensitive medical/dental devices such as endoscopes, respiratory therapy equipment and ultrasonic transducers.

Sterilant:
CIDEX Solution is a sterilant when used or reused, according to the Directions for Use, at or above its Minimum Effective Concentration (MEC) as determined by the CIDEX® Solution Test Strip, at 25°C (77°) with an immersion time of at least 10 hours with a reuse period not to exceed 14 days.

High Level Disinfectant:
CIDEX Solution is a high level disinfectant when used or reused, according to the Directions for Use, at or above its Minimum Effective Concentration (MEC) as determined by the CIDEX® Solution Test Strip, at 25°C (77°) with an immersion time of at least 45 minutes with a reuse period not to exceed 14 days.

CIDEX Solution is intended for use in manual systems as well as in automated endoscope reprocessors.

Description of Modification

The modification to the device incorporates an anti-oxidant and solubilizing agent to increase the shelf life of the product beyond the current 2 years.

Summary of Non-clinical Tests

Microbiological activity of the Modified Device was evaluated using the required standard test methods. The sterilization claim and high level disinfection claim for the Modified Device was confirmed to be the same as the Predicate Device.

Simulated use studies were conducted to validate the sterilization and high-level disinfection claim. The external surface and internal lumens of three types of endoscopes were inoculated with $>10^6$ cfu *Bacillus subtilis* spores and subjected to 10 hours soaking at 25°C. Sampling of the surface and lumens indicated a $>10^6$ log reduction in viable spores. High-level disinfection was verified in a simulated use study using the same three types of scopes whose surfaces and internal lumens were inoculated with $>10^6$ cfu *Mycobacterium terrae*. Exposure to the Modified Device for 45 min at 25°C reduced the viable *M. terrae* by $>6\log_{10}$.

Stability studies of the Modified Device are in progress. Accelerated stability studies (40°C/75%RH) indicate that the product is stable for 6 months, and increase over the stability of the Predicate Device. Real time stability

(30°C/60%RH) is on going. Data at 18 months indicates the product is stable. Data will be collected out to 3 years.

Substantial Equivalence

Based on the data obtained from the studies described above, the Modified Device, CIDEX Activated Dialdehyde Solution is substantially equivalent to the Predicate Device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 12 2006

Dr. Joseph M. Ascenzi
Senior Manager, Regulatory Affairs
Advanced Sterilization Products
Johnson & Johnson Company
Division of Ethicon, Incorporated
33 Technology Drive
Irvine, California 92618

Re: K060618
Trade/Device Name: CIDEX® Activated Dialdehyde Solution
Regulation Number: 880.6885
Regulation Name: Liquid Chemical Sterilants/High Level Disinfectants
Regulatory Class: II
Product Code: MED
Dated: March 28, 2006
Received: March 29, 2006

Dear Dr. Ascenzi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: CIDEX® Activated Dialdehyde Solution

Indications for Use:

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High Level Disinfectant:

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CIDEX Solution is intended for use in manual systems as well as in automated endoscope reprocessors.

Prescription Use _______ (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use ___√___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

4/12/06

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